IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015 (GBW) [redacted]
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC. Plaintiff/Counter-Defendants.	REDACTED - PUBLIC VERSION

CONCISE STATEMENT OF FACTS IN SUPPORT OF SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN AUSTRALIA'S MOTIONS FOR SUMMARY JUDGMENT

[redacted]

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[redacted]

TABLE OF ABBREVIATIONS

Abbreviation	Description
'851 Patent	U.S. Patent No. 9,994,851
'590 Patent	U.S. Patent No. 10,227,590
'827 Patent	U.S. Patent No. 10,266,827
'851 Pat. PH Excerpt	Excerpts of the prosecution history for U.S. Patent No. 9,994,851
'590 Pat. PH Excerpt	Excerpts of the prosecution history for U.S. Patent No. 10,227,590
'827 Pat. PH Excerpt	Excerpts of the prosecution history for U.S. Patent No. 10,266,827
'150 Appl. PH Excerpt	Excerpts of the prosecution history for U.S. Patent Application No. 13/741,150
0644 CERI Rpt.	[redacted]
0661 CERI Rpt.	[redacted]
ASO	Antisense oligonucleotide
Clemens 2020	Clemens et al., "Safety Tolerability, and Efficacy of Viltolarsen in Boys With Duchenne Muscular Dystrophy Amenable to Exon 53 Skipping," JAMA Neurology (2020):E1-E10
Dowdy Op. Rpt.	Opening Expert Report of Steven F. Dowdy, Ph.D., dated September 7, 2023
Esau Reb. Rpt.	Rebuttal Expert Report of Christine C. Esau, Ph.D Regarding Non-Infringement of the UWA Patents, dated October 11, 2023
Esau Tr.	Transcript of Christine Esau Deposition held November 3, 2023, in *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc. et al.*, No. 1:21-cv-01015-GBW (D. Del.)
Ex. ____	Exhibit ____[1]
Fletcher Tr.	Transcript of Sue Fletcher Deposition held September 27, 2023, in *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc. et al.*, No. 1:21-cv-01015-GBW (D. Del.)

[1] Refers to Exhibits to the accompanying Declaration of Megan E. Dellinger in Support of Sarepta Therapeutics, Inc. and The University of Western Australia's Motions for Summary Judgment and Motions to Exclude Certain Opinions and Testimony of Plaintiff/Counter-Defendants' Experts.

[redacted]

Abbreviation	Description
Kamholz Op. Rpt.	Expert Report of Scott E. Kamholz, Esq., dated September 8, 2023
Gendron Tr.	Transcript of Gardner Gendron Deposition held July 11, 2023, in *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc. et al.*, No. 1:21-cv-01015-GBW (D. Del.)
Hastings Op. Rpt.	Expert Report of Dr. Michelle L. Hastings Regarding Invalidity of the UWA Patents, dated September 8, 2023
Hastings Tr.	Transcript of Michelle Hastings, Ph.D. Deposition held November 17, 2023, in *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc. et al.*, No. 1:21-cv-01015-GBW (D. Del.)
Hosfield Op. Rpt.	Expert Report and Disclosure of Mark J. Hosfield, dated September 8, 2023
Hosfield Tr.	Transcript of Mark Hosfield Deposition held November 1, 2023, in *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc. et al.*, No. 1:21-cv-01015-GBW (D. Del.)
Kamholz Reply Rpt.	Reply Expert Report of Scott E. Kamholz, Esq., dated October 27, 2023
Kamholz Tr.	Transcript of Scott E. Kamholz Esq. Deposition held November 3, 2023, in *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc. et al.*, No. 1:21-cv-01015-GBW (D. Del.)
NS	Plaintiff/Counter-Defendants Nippon Shinyaku Co., Ltd. and NS Pharma, Inc.
NS Final Non-Infringement Contentions	Nippon Shinyaku Co. Ltd. and NS Pharma, Inc.'s Noninfringement Contentions, served July 11, 2023
NS Japan	Plaintiff/Counter-Defendant Nippon Shinyaku Co., Ltd.
NS Pharma	Counter-Defendant NS Pharma, Inc.
NS Response to ROG 35	Nippon Shinyaku Co. Ltd. and NS Pharma, Inc.'s First Supplemental Responses and Objections to Sarepta Therapeutics, Inc.'s Interrogatory No. 35, served August 15, 2023
PTO	United States Patent and Trademark Office
Sarepta	Defendant/Counter-Plaintiff Sarepta Therapeutics, Inc.
Takeda 2021	Takeda et al., "Exon-Skipping in Duchenne Muscular Dystrophy," J. Neuromuscl. Dis. (2021) 8:S343-S358
Toda Tr.	Transcript of Masaya Toda Deposition held June 28-29, 2023, in *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc. et al.*, No. 1:21-cv-01015-GBW (D. Del.)
UWA	Counter-Plaintiff The University of Western Australia
Viltepso® Label	Viltepso® (viltolarsen) Prescribing Information (Revised: 3/2021)

[redacted]

Abbreviation	Description
Watanabe Tr.	Transcript of Naoki Watanabe Deposition held June 26-27, 2023, in *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc. et al.*, No. 1:21-cv-01015-GBW (D. Del.)
Wilton Patents	U.S. Patent Nos. 9,994,851; 10,227,590; and 10,266,827
Wilton Product Patents	U.S. Patent Nos. 9,994,851; 10,227,590
Wilton Tr.	Transcript of Steve Wilton Deposition held June 15, 2023, in *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc. et al.*, No. 1:21-cv-01015-GBW (D. Del.)

[redacted]

I. *STATEMENT OF FACTS IN SUPPORT OF MOTION #1*: SUMMARY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NOS. 9,994,851 AND 10,227,590

A. Structure of Viltepso® (Viltolarsen) and the Wilton Product Patents: U.S. Patent Nos. 9,994,851 ("the '851 Patent") and 10,227,590 ("the '590 Patent")

1.1. Each of the claims of the Wilton Product Patents recites an "antisense oligonucleotide of 20 to 31 bases." Ex. 1 ['851 Patent], claims 1-2; Ex. 2 ['590 Patent], claims 1-2.

1.2. Viltepso® (viltolarsen) is an antisense oligonucleotide having 21 bases. *See, e.g.*, Ex. 44 [Viltepso® Label], § 11 ("Viltolarsen is an antisense oligonucleotide . . . . Viltolarsen contains 21 linked subunits.").

1.3. Each of the claims of the Wilton Product Patents recites that "the antisense oligonucleotide is a morpholino antisense oligonucleotide." Ex. 1 ['851 Patent], claims 1-2; Ex. 2 ['590 Patent], claims 1-2.

1.4. Viltepso® is a morpholino antisense oligonucleotide. *See, e.g.*, Ex. 44 [Viltepso® Label], § 11 ("Viltolarsen is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass.").

1.5. Each of the claims of the Wilton Product Patents recites that the claimed ASO "compris[es] a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA." As construed by the Court, the term "a base sequence" means "any sequence of bases that is part of the antisense oligonucleotide." D.I. 249 at 1. As construed by the Court, the terms "a target region" and "exon 53 of the human dystrophin pre-mRNA" respectively mean "a segment of the pre-mRNA" and "the pre-mRNA transcribed from exon 53 of the human dystrophin gene." *Id.* at 2.

1.6. Viltepso® contains a sequence of bases that is part of the antisense oligonucleotide. Ex. 44 [Viltepso® Label], § 11 (listing the base sequence of Viltepso® as

[redacted]

"CCTCCGGTTC TGAAGGTGTT C"). The base sequence of Viltepso® is also 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA. Ex. 45 [Takeda 2021], S351 (describing Viltepso® as "a 21 nucleotide PMO, named NS-065/NCNP-1 (viltolarsen), located between positions 36 and 56 . . . of exon 53"); Ex. 41 [Watanabe Tr.], 34:2-35:5 ([redacted]).

1.7. Each of the claims of the Wilton Product Patents recites that "the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195), in which uracil bases are thymine bases." Ex. 1 ['851 Patent], claims 1-2; Ex. 2 ['590 Patent], claims 1-2.

1.8. As construed by the Court, the term "in which uracil bases are thymine bases" means that "the antisense oligonucleotide has thymine bases instead of uracil bases." D.I. 249 at 2; D.I. 248 at 28-29.

1.9. The Court explained the term "in which uracil bases are thymine bases" refers "to the entire [ASO]." D.I. 248 at 28. The Court further explained that the "prosecution history also demonstrates that the Examiner understood that the disputed term was intended to modify the entire [ASO], not just the preceding base sequence limitation." *Id.*

1.10. The base sequence of Viltepso® contains only thymine bases and no uracil bases [redacted]. *See, e.g.*, Ex. 21 [Esau Reb. Rpt.], ¶¶28, 32-33, 45; Ex. 31 [Esau Tr.], 30:16-31:6, 31:12-16.

[redacted]

1.11. Each of the claims of the Wilton Product Patents recites that "the antisense oligonucleotide induces exon 53 skipping." Ex. 1 ['851 Patent], claims 1-2; Ex. 2 ['590 Patent], claims 1-2.

1.12. Viltepso® induces exon 53 skipping. *See, e.g.*, Ex. 46 [Clemens 2020], E4 ("[redacted]"); Ex. 41 [Watanabe Tr.], 37:17-23.

1.13. In addition to the common structural features above, claims 1 and 2 of the '851 Patent recite that "the target region is within annealing site H53A(+23+47) and annealing site H53A(+39+69)." Ex. 1 ['851 Patent], claims 1-2. As construed by the Court, this term means that "the target region is within nucleotides +23 to +69 of exon 53 of the human dystrophin pre-mRNA." D.I. 249 at 2.

1.14. The target region for Viltepso® (nucleotides +36+56) falls within the target region of nucleotides +23+69 of the human dystrophin pre-mRNA. *See, e.g.*, Ex. 45 [Takeda 2021], S351 ([redacted]); Ex. 41 [Watanabe Tr.], 34:2-35:5.

1.15. In addition to the common structural features above, claim 2 of the '851 Patent and claim 2 of the '590 Patent recite "a pharmaceutical composition" comprising "a pharmaceutically acceptable carrier." Ex. 1 ['851 Patent], claim 2; Ex. 2 ['590 Patent], claim 2. The Wilton Product Patents state that "[w]ater or saline solutions . . . are perfectly employed as carriers, particularly for injectable solutions." Ex. 1 ['851 Patent], 28:45-57.

1.16. Viltepso® is a pharmaceutical composition comprising viltolarsen, sodium chloride (salt), and water. *See, e.g.*, Ex. 44 [Viltepso® Label], § 11 ("Each milliliter of VILTEPSO contains 50 mg viltolarsen and 9 mg sodium chloride in water for injection.").

[redacted]

B. Nippon Shinyaku Co., Ltd. ("NS Japan") and NS Pharma, Inc. ("NS Pharma") (collectively, "NS") Have Sold Viltepso® in the United States

1.17. [redacted] *See, e.g.*, Ex. 39 [Gendron Tr.], 84:6-10 ([redacted]); Ex. 40 [Toda Tr.], 59:13-60:6 [redacted]; Ex. 43, NS00036879-81 ([redacted]); Ex. 42, NS00036966-67 ([redacted]).

1.18. NS Pharma has sold Viltepso® in the United States. *See, e.g.*, Ex. 39 [Gendron Tr.], 85:20-86:7 ([redacted]), 54:25-59:7 ([redacted]), 158:22-159:20 (same); Ex. 43, NS00036879-81 ([redacted]); Ex. 42, NS00036966,-67 ([redacted]). [redacted] Ex. 13 [NS Response to ROG 35]; Ex. 39 [Gendron Tr.], 86:1-7.

C. Expert Testimony Addressing Whether Viltepso® Meets the Limitations of the Wilton Product Patents

1.19. Sarepta Therapeutics, Inc.'s expert Dr. Steven Dowdy has opined that NS's Viltepso® meets every limitation of the claims of the Wilton Product Patents. *See* Ex. 18 [Dowdy Op. Rpt.], ¶¶234-265, 270-272, 274-283, 297.

1.20. In her Rebuttal Expert report, NS's expert Dr. Christine Esau argues that [redacted]. *See, e.g.*, Ex. 21 [Esau Reb. Rpt.], ¶¶23-48, 63-64. Dr. Esau contends that Viltepso® does not meet the limitation "[redacted]" *Id.* ¶¶32-33.

[redacted]

1.21. Dr. Esau has not identified any other basis for her opinion that VILTEPSO does not meet every limitation of the Wilton Product Patents. *See, e.g.*, Ex. 31 [Esau Tr.], 30:16-31:6, 31:12-16, 39:14-40:17.

1.22. No other NS expert has identified any other basis for the assertion that VILTEPSO does not meet every limitation of the Wilton Product Patents.

1.23. Dr. Esau acknowledges that her proposed construction of the limitation "wherein the base sequence comprises at least 12 consecutive bases of [SEQ ID NO: 195]" [redacted] *See* Ex. 31 [Esau Tr.], 33:2-10.

1.24. Dr. Esau acknowledges that [redacted], Ex. 21 [Esau Reb. Rpt.], ¶28, and that Viltepso® [redacted], Ex. 21 [Esau Reb. Rpt.], ¶¶32-33; Ex. 31 [Esau Tr.], 30:16-31:6, 31:12-16, 39:14-40:17.

1.25. Dr. Esau acknowledges that Viltepso® meets the limitation [redacted] Ex. 21 [Esau Reb. Rpt.], ¶45.

1.26. NS's expert Dr. Hastings [redacted] Ex. 32 [Hastings Tr.], 157:11-158:15.

1.27. [redacted]

[redacted] Ex. 22 [Hastings Op. Rpt.], ¶101; Ex. 47 [0644 CERI Rpt.], Table 1 (NS00102991-94); Ex. 48 [0661 CERI Rpt.], Table 1 (NS00103064-66).

1.28. Dr. Esau [redacted] Ex. 31 [Esau Tr.], 31:24-33:1.

D. NS's Final Non-Infringement Contentions and Pleadings

1.29. The only basis identified in NS's Final Non-Infringement Contentions for the assertion that Viltepso® does not meet every limitation of the claims of the Wilton Product Patents is that Viltepso® does not meet the limitation [redacted]." Ex. 12 [NS Final Non-Infringement Contentions], 5-10.

1.30. NS's Answer to Counter-Plaintiffs' Amended Counterclaims identifies no other basis for the assertion that Viltepso® does not meet every limitation of the Wilton Product Patents. *See* D.I. 344 at 14-21.

[redacted]

II. *STATEMENT OF FACTS IN SUPPORT OF MOTION #2*: SUMMARY JUDGMENT OF NO LOST PROFITS

A. Plaintiff NS Japan and Non-Party NS Pharma Are Distinct Corporate Entities

2.1. Nippon Shinyaku Co. Ltd. ("NS Japan"), the entity that asserted infringement claims against Sarepta, is a Japanese company with a principal place of business in Japan. D.I. 86 at ¶4. NS Pharma, Inc. ("NS Pharma") is its wholly-owned subsidiary. D.I. 324 at ¶¶5-7; *see also* Ex. 49 [Hosfield Op. Rpt.], pgs. 7-8. NS Pharma is a distinct entity existing under the laws of Delaware with a principal place of business in New Jersey. D.I. 324 at ¶7; *see also* Ex. 49 [Hosfield Op. Rpt.], pg. 8.

2.2. NS Pharma is not a plaintiff in NS Japan's claims for infringement in this case. *See, e.g.,* D.I. 324 at 1.

B. [redacted]

2.3. [redacted]. *See* Ex. 53, NS00036893; *see also* Ex. 49 [Hosfield Op. Rpt.], pgs. 23-24.

2.4. Since its launch, [redacted] in the United States. Ex. 49 [Hosfield Op. Rpt.], pg. 60; Ex. 50 [Hosfield Tr.], 112:11-14; *see also* Ex. 53, NS00036894.

C. [redacted]

2.5. [redacted]" Ex. 53, NS00036894; *see also* Ex. 50 [Hosfield Tr.], 114:16-19, 115:7-15; Ex. 40 [Toda Tr.], 59:13-60:2.

[redacted]

2.6. [redacted]

[redacted]" Ex. 53, NS00036898; *see also* Ex. 49 [Hosfield Op. Rpt.], pg. 24.

2.7. [redacted]" *See* Ex. 49 [Hosfield Op. Rpt.], pgs. 24-25.

D. [redacted]

2.8. [redacted]" Ex. 53, NS00036897; *see also* Ex. 49 [Hosfield Op. Rpt.], pg. 24 ("[redacted]").

2.9. [redacted] Ex. 53, NS00036897; *see also* Ex. 49 [Hosfield Op. Rpt.], pg. 24.

2.10. [redacted]" *Id.*; *see also* Ex. 49 [Hosfield Op. Rpt.], pg. 24.

[redacted]

2.11. There is no evidence in the record that [redacted] Ex. 50 [Hosfield Tr.], 114:9-15. [redacted] ” Ex. 53, NS00036898; *see also id.* (instructing [redacted] ”).

2.12. [redacted] *See* Ex. 49 [Hosfield Op. Rpt.], pg. 81; *see also* Ex. 39 [Gendron Tr.], 110:3-8, 79:8-80:25 ([redacted]).

E. [redacted]

2.13. Mr. Hosfield's lost profits analysis is [redacted] *See* Ex. 49 [Hosfield Op. Rpt.], pgs. 60, 79-81; *see also* Ex. 50 [Hosfield Tr.], 112:15-113:3.

2.14. [redacted] ” Exs. 51 & 52, NS00065827.

2.15. [redacted] Ex. 53, NS00036897-98; *see also* Ex. 49 [Hosfield Op. Rpt.], pg. 24.

[redacted]

2.16. Mr. Hosfield admitted that [redacted] *See* Ex. 50 [Hosfield Tr.], 120:24-121:11 ("[redacted]").

2.17. Neither NS Japan nor NS Pharma have produced evidence of [redacted].

[redacted]

III. *STATEMENT OF FACTS IN SUPPORT OF MOTION #3*: SUMMARY JUDGMENT OF NO INEQUITABLE CONDUCT AND NO *WALKER PROCESS* FRAUD

3.1. The PCT application to which the Wilton Patents claim priority (PCT/AU2005/000943, "the 2005 PCT Application") was filed on June 28, 2005. Ex. 11, item (22).

3.2. On March 26, 2013, in connection with U.S. Patent Application No. 13/741,150 ("the '150 Application"), which claimed priority to the 2005 PCT Application, Dr. Wilton and Dr. Fletcher signed an inventorship declaration that was subsequently submitted to the PTO during prosecution of that application. Ex. 17 ['150 Appl. PH Excerpt], SRPT-VYDS-0134063-65.

3.3. On September 14, 2017, UWA filed U.S. Patent Application No. 15/705,172 (the '172 Application"). Ex. 14 ['851 Pat. PH Excerpt], SRPT-VYDS-0002985-3098.

3.4. The '172 Application claimed priority to both the '150 Application and the 2005 PCT Application. Ex. 15 ['851 Pat. PH Excerpt], SRPT-VYDS-0002991-99, -3022.

3.5. Pursuant to 37 C.F.R. § 1.63(d)(1), the March 26, 2013 inventorship declaration was also submitted during prosecution of the '172 Application. Ex. 15 ['851 Pat. PH Excerpt], SRPT-VYDS-0002988-90.

3.6. On September 22, 2017, Ms. Mandragouras submitted Harding et al. "The Influence of Antisense Oligonucleotide Length on Dystrophin Exon Skipping," *Molecular Therapy*, Vol. 15, No. 1, 157-166 (2007) ("the Harding paper") to the PTO in an Information Disclosure Statement. Ex. 15 ['851 Pat. PH Excerpt], SRPT-VYDS-0003156-63 (Form PTO/SB/08a) at -57.

3.7. The Examiner considered the Harding paper in the course of her examination of the '172 Application, as reflected by the Examiner's initials at the bottom of each page of the IDS along with her annotation "ALL REFERENCES CONSIDERED EXCEPT WHERE LINED

[redacted]

THROUGH." Ex. 15 ['851 Pat. PH Excerpt], SRPT-VYDS-0004648-55 (Form PTO/SB/08a Considered) at -49.

3.8. The '172 Application issued as the '851 patent on May 23, 2018. Ex. 15 ['851 Pat. PH Excerpt], SRPT-VYDS-0004980.

3.9. On March 28, 2018, a different law firm took over prosecution of the '172 Application and Ms. Mandragouras's involvement in that application ceased. Ex. 15 ['851 Pat. PH Excerpt], SRPT-VYDS-0004929-34.

3.10. That firm also prosecuted the applications that issued as the '590 and '827 patents. Ex. 16 ['590 Pat. PH Excerpt], SRPT-VYDS-0005352-53, -603-609; Ex. 17 ['827 Pat PH Excerpt], SRPT-VYDS-0006187-88, -244-50.

3.11. On August 24, 2018, UWA filed the application that ultimately issued as the '590 patent. Ex. 16 ['590 Pat. PH Excerpt], SRPT-VYDS-0005243-374.

3.12. On August 24, 2018, UWA filed the applications that ultimately issued as the '827 patent. Ex. 17 ['827 Pat PH Excerpt], SRPT-VYDS-0005994-6229.

3.13. The Harding paper was submitted to the PTO during prosecution of the application that ultimately issued as the '590 patent. Ex. 16 ['590 Pat. PH Excerpt], SRPT-VYDS-0005451-561 (Form PTO/SB/08a) at -479.

3.14. The Examiner indicated that she considered the Harding paper during her examination of the application that ultimately issued as the '590 patent. Ex. 16 ['590 Pat. PH Excerpt], SRPT-VYDS-0005626-737 (Form PTO/SB/08a Considered) at -729; *id.* SRPT-VYDS-0005750.

[redacted]

3.15. The Harding paper was submitted to the PTO during prosecution of the application that ultimately issued as the '827 patent. Ex. 17 ['827 Pat PH Excerpt], SRPT-VYDS-0006287-398 (Form PTO/SB/08a) at -315.

3.16. The Examiner indicated that she considered the Harding paper during her examination of the application that ultimately issued as the '827 patent. Ex. 17 ['827 Pat PH Excerpt], SRPT-VYDS-0006478-589 (Form PTO/SB/08a Considered) at -506; *id.* SRPT-VYDS-0006604.

3.17. In his expert reports, NS's patent law expert Dr. Kamholz repeatedly opines as to what Dr. Wilton, Dr. Fletcher, and Ms. Mandragouras "knew or should have known." Ex. 24 [Kamholz Op. Rpt.], ¶¶32-33, 36-37, 55, 73, 78-79; Ex. 26 [Kamholz Reply Rpt.], ¶¶2, 12, 17, 21, 27, 29-30.

3.18. Dr. Kamholz testified that it is his opinion that the inventors and Ms. Mandragouras "knew or should have known" [redacted] Ex. 33 [Kamholz Tr.], 48:18-49:7, 49:18-50:5; Ex. 24 [Kamholz Op. Rpt.], ¶33.

3.19. Dr. Kamholz testified that it is not his opinion that inventors Dr. Wilton and Dr. Fletcher, or patent attorney Ms. Mandragouras, [redacted] Ex. 33 [Kamholz Tr.], 48:3-13, 49:8-13, 50:21-24.

3.20. Dr. Kamholz asserts that the inventors and Ms. Mandragouras "knew or should have known" [redacted] Ex. 24 [Kamholz Op. Rpt.], ¶¶36-37; Ex. 26 [Kamholz Reply Rpt.], ¶12.

3.21. Dr. Kamholz [redacted] Ex. 33 [Kamholz Tr.], 79:10-13, 79:18-21, 80:1-4.

[redacted]

3.22. [redacted]

[redacted] Ex. 38 [Wilton Tr.], 152:20-153:6.

3.23. [redacted]

[redacted] Ex. 36 [Fletcher Tr.], 200:1-3.

3.24. [redacted]

[redacted] Ex. 36 [Fletcher Tr.], 200:5-9.

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December 11, 2023

CERTIFICATE OF SERVICE

I hereby certify that on December 11, 2023, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on December 11, 2023, upon the following in the manner indicated:

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